Effect of Polyethylene Crosslinking on the Wear Performance of the Zimmer® Trabecular Metal™ Ankle

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ABSTRACT

Purpose. The goal of this study was to quantify the improvement in wear performance of the Zimmer® Trabecular Metal™ Ankle that can be attributed to use of Prolong® highly crosslinked polyethylene.

Methods. Wear simulations were performed on the TM Ankle using kinetic and kinematic inputs consistent with normal gait. Tibial articular surfaces were manufactured to the same geometry from both Prolong highly-crosslinked polyethylene and from conventional polyethylene (six samples each, with two load soak controls for each polyethylene). Simulations were conducted to 5.0 Mc, with weight loss measurements performed at regular intervals.

Results. A mean gravimetric wear rate of 1.9 ± 0.3 mg/Mc was measured for components manufactured from Prolong UHMWPE, as compared to a mean gravimetric wear rate of 7.4 ± 1.2 mg/Mc for components manufactured from non-crosslinked polyethylene.

Conclusion. Use of Prolong UHMWPE within the Zimmer TM Ankle design results in a wear rate reduction of 74%, as compared to use of conventional UHMWPE in the same design.

1. INTRODUCTION

Total ankle arthroplasty (TAA) is an established procedure for replacing the native articulating surfaces of the ankle joint with implant systems designed to restore mobility through use of synthetic bearing couples. Typically, these bearing couples utilize cobalt chromium alloys articulating on ultrahigh molecular weight polyethylene (UHMWPE). Articulation of these surfaces during in vivo loading can generate UHMWPE wear particles, which may then result in osteolysis and component loosening. Studies have reported observations of osteolysis following TAA in 15-22% of patient populations. Use of highly crosslinked UHMWPE has been shown to reduce wear in other joint systems and thus has the potential to improve wear performance of TAA.

2. MATERIALS AND METHODS

2.1 Materials

Midrange (size 3) samples of the TM Ankle (right side) were selected for testing. The talar components were machined from wrought Zimaloy® Cobalt Chrome Molybdenum (CoCrMo) alloy and have a Trabecular...
Metal (TM) porous surface diffusion bonded via an interlayer of commercially pure titanium. The tibial baseplate components were machined from wrought Tivanium® (Ti-6Al-4V) alloy with a diffusion bonded Trabecular Metal porous surface. Modular UHMWPE articular surfaces were machined from Prolong. Articular surfaces were also machined from GUR 1050 stock, strictly for purposes of this research study (GUR 1050 articular surfaces are not cleared for clinical use). All polyethylene samples were packaged and subjected to ethylene oxide sterilization, per standard production processing. Six TM Ankle constructs for each polyethylene (n=6) were tested, with an additional two constructs each used for load soak controls.

2.2 Methods

All experiments were conducting using an AMTI™ Knee (Advanced Mechanical Technology, Inc., Waltham, MA) joint simulator with SIMMAC™ control software.

2.2.1 Test setup and environment

A schematic of the wear test setup is shown in Figure 2. Talar components were mounted to the simulator arbor using bone cement, at a fixed 8° angle relative to the axis of ankle rotation. Tibial baseplates were mounted into a custom fixture using adhesive. This configuration enabled independent control of flexion/extension and anterior/posterior (AP) translation (through the talar arbor), as well as load and internal/external (IE) rotation (through the tibial fixture). Additionally, use of roller bearings beneath the tibial support fixture enabled passive varus/valgus rotation in response to the other prescribed loading and boundary conditions.

2.2.2 Biomechanical loading

Applied loads and boundary conditions for the wear simulation were based on the physiological profiles of Bell et al. and are shown in Figure 3. A peak load of 3188 N (717 lb) was used, representing approximately three times body weight for a 109 kg (239 lb) patient; a minimum load of 200 N (45 lb) was applied during swing phase in order to ensure constant tibiotalar contact. Flexion ranged from 16° of plantarflexion (−) to 15.2° of dorsiflexion (+), in agreement with ASTM F2665-09. IE rotation ranged from 2° external (−) talar rotation to 8° internal (+) talar rotation. Finally, AP translation ranged from 1.5 mm posterior (−) translation to 1.5 mm anterior (+) translation, with the same shape as the flexion curve of Bell. All tests were run at a physiological frequency of 1.1 Hz.

2.2.3 Sample processing

All specimens were disassembled every 0.5 Mc for cleaning and weighing. In order to remove the polyethylene insert from the tibial baseplate without damaging the locking mechanism, each tibial fixture was immersed in liquid nitrogen for 45-60 seconds. The weight of each specimen, including the load soak controls, was measured every 0.5 Mc from 0 to 3.0 Mc, and every 1.0 Mc from 3.0 to 5.0 Mc. Test lubricant was salvaged at 1.0 Mc and 3.0 Mc for debris analysis. Photographs of the articulating surfaces were taken and each surface was visually inspected for signs of wear.

Diluted bovine calf serum, prepared at a protein concentration of 20 mg/mL, was used as test lubricant. Each articulating couple was tested in an environmentally sealed chamber inside of which the lubricant was recirculated and maintained at 37 ± 3 °C. Samples were rotated between stations of the simulator at each 0.5 million cycles (Mc), in order to minimize station-to-station effects on overall wear rate.
2.2.4 Data analysis

The ability of polyethylene to absorb fluid may confound wear measurements based on sample weight. In order to account for fluid absorption, the change in weight of the articulating components was offset by the change in weight of the load soak controls. The resulting weight loss measurements from 0.5 – 5.0 Mc were linearly regressed against cycle time to calculate cumulative wear rate and statistically significant differences between the wear rates were assessed using a Student’s t-test (p ≤ 0.05).

3. RESULTS

Weight loss values as a function of cycle count, as well as the average linear wear for each material after run-in, are shown in Figure 4. (Note that three samples for each material were weighed at 1.6 Mc rather than 1.5 Mc and at 3.04 Mc rather than 3.0 Mc.) Linear gravimetric wear rates were 7.4 ± 1.2 mg/Mc for conventional UHMWPE and 1.9 ± 0.3 mg/Mc for Prolong UHMWPE, respectively (p < 0.05), representing a 74% decrease in average gravimetric wear rate due to use of crosslinked UHMWPE.

The volumetric wear rates for several TAA devices have been reported in the literature under similar in vitro loading conditions: Buechel-Pappas Ankle (Endotec, Inc.) and Mobility™ Ankle (Depuy Orthopaedics, Warsaw, IN). These reports include volumetric wear rates for wear simulations both with and without AP translation. The reported rates for these devices, as well as the volumetric wear rate for Prolong UHMWPE (assuming a density of 0.93 mg/mm³) based on the data reported here, are shown in Table 1, indicating improved wear performance of the Zimmer TM Ankle relative to these devices. Note that there is not sufficient information in the published reports to assess whether the differences between devices are statistically significant, or whether differences in wear performance can be attributed to essential design differences (geometry and/or material), differences in test methodology (including component size and loading conditions), or a combination of the two. Additionally, note that in vitro testing of the BOX® Ankle (Finsbury Orthopaedics Ltd., Surrey, UK) has been reported but the tests used a non-physiological lubricant (deionized water) results from that study are therefore not reported here.

Key parameters of the in vitro ankle wear test here and from studies reported in the literature are summarized in Table 2. All previous studies utilized three samples per device; here, six samples were used. The current study utilized an AP translation of 3mm for 5.0 Mc, whereas Bell et al. incorporated 3mm of AP translation for 1.0 Mc. The methodology of Affatato et al. incorporated increased AP translation (8.45mm) but at a much reduced peak load (1.6kN) and for only 2.0 Mc. The current study thus incorporates the most strenuous in vitro test environment for wear evaluation of ankle prostheses. A more comprehensive presentation of this study is now available in the peer-reviewed literature.

![Figure 4. Weight loss as a function of cycle count.](image)

<table>
<thead>
<tr>
<th>Device</th>
<th>AP translation (mm)</th>
<th>Volumetric wear rate (mm³/Mc)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zimmer TM Ankle</td>
<td>3.0</td>
<td>2.1 ± 0.4</td>
</tr>
<tr>
<td>Buechel-Pappas</td>
<td>3.0</td>
<td>16.4 ± 17.4</td>
</tr>
<tr>
<td>Buechel-Pappas</td>
<td>0</td>
<td>10.4 ± 11.8</td>
</tr>
<tr>
<td>Mobility</td>
<td>3.0</td>
<td>10.4 ± 14.7</td>
</tr>
<tr>
<td>Mobility</td>
<td>0</td>
<td>3.4 ± 10.0</td>
</tr>
</tbody>
</table>

Table 1. Volumetric wear rates for the TM Ankle and as reported for other TAA devices, with 95% confidence intervals.

<table>
<thead>
<tr>
<th>Number of samples</th>
<th>Bell et al.</th>
<th>Affatato et al.</th>
<th>Zimmer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum load</td>
<td>3.1 kN</td>
<td>1.6 kN</td>
<td>3.2 kN</td>
</tr>
<tr>
<td>Flexion</td>
<td>30° (-15° → 15°)</td>
<td>30° (-10° → 20°)</td>
<td>31.2° (-16° → 15.2°)</td>
</tr>
<tr>
<td>IE rotation</td>
<td>10° (-2° → 8°)</td>
<td>10.3° (-2.6° → 7.7°)</td>
<td>10° (-2° → 8°)</td>
</tr>
<tr>
<td>AP translation</td>
<td>0 mm</td>
<td>3 mm</td>
<td>8.45 mm</td>
</tr>
<tr>
<td>Number of cycles</td>
<td>5.0 Mc</td>
<td>1.0 Mc</td>
<td>2.0 Mc</td>
</tr>
</tbody>
</table>

Table 2. Comparative analysis of biomechanical parameters used for ankle wear testing (sign conventions are as indicated in 2.2.2).
4. CONCLUSIONS

Improvement in total ankle arthroplasty device design, including both articulating surface geometry and material selection of the bearing couple, has the potential to significantly reduce polyethylene wear in vivo. Here, the improvements in wear that can be attributed to use of highly crosslinked UHMWPE (Prolong), rather than conventional (non-crosslinked) UHWMPE, within the Zimmer TM Ankle implant geometry has been quantified using in vitro wear testing. After 5 Mc of testing, use of Prolong UHMWPE has resulted in a 74% decrease in wear, as compared to the same device manufactured from conventional UHMWPE.

References


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